K072598

APR 14 2008

510(k) Summary Pertaining to the Safety and Effectiveness of the IRSG Bed Mover

Date Summary Prepared: August 28, 2007

Submitter:
International Retail Services Group, LLC
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Name of Device: IRSG Bed Mover
Common name of device: Bed mover
Classification name device: "AC powered Adjustable Bed 21 CFR 880.5100, Class II, FNL" and "Wheeled Stretcher" 21 CFR 880.6910, Class II, FPO

Predicate Device (s):
Stryker Powered Wheeled Stretcher with Zoom™ Drive Wheel AND
Paramed Systems Paraglyde™ DCS TM-1

Device Description:
The IRSG i-mover for beds is a battery-powered, temporary accessory to most wheeled hospitals beds and stretchers. It is unit operated by a single caregiver to assist in the movement of most wheeled hospital beds and stretchers commonly used within a healthcare facility.

Only the caregiver, not the patient, can control this powered assistive device.

This device is not permanently attached to or made a part of the stretcher or bed.

The FDA has classified this device as an accessory to the wheeled bed or stretcher which the device will assist in moving. These beds and stretchers are Class I (hydraulic or manual beds) and Class II (powered adjustable beds and wheeled stretchers). The FDA has classified this device as a Class I device when used with non-patient laden beds and a Class II device when assisting in movement of a patient-laden bed.

Intended Use
The IRSG bed mover is intended to assist a single caregiver in the moving of wheeled beds and stretchers from one location to another within the healthcare facility. The bed mover may be used with both patient-laden or non patient-laden beds / stretchers.

Device Comparison:
The IRSG bed mover is substantially equivalent to the Stryker Zoom™ Motorized Stretchers ,(i.e. with the Stryker Powered Wheeled Stretcher with a drive option)K022309 and the Paramed Systems Paraglyde™ DCS – TM1 (FPO, 880.6910, Class II, 510k exempt) in function, technological characteristics and intended use.

The minor differences described in the submission between the IRSG bed mover and the predicate devices do not raise any new issues of safety or effectiveness. The intended use, basic movement technology and performance characteristics of the devices are the same.

The IRSG i-mover for beds does not contact the patient, so biocompatibility is not a concern.

The subject assistive device is intended for use in the same clinical environment where patient care is administered. Health facilities ordinarily use powered stretchers or beds for patient transportation to and from treatment modalities i.e. physical therapy, diagnostic radiation, etc.)

The labels and labeling (operators and maintenance manuals) provide information for the safe operation by the caregiver / user and the intended operation features.

The bed mover will comply with the following voluntary standards

IEC 60601-1, medical Electrical Equipment – Part 1 : General Requirements for Safety, 1988 (General), Amendment 1, 19991-11, Amendment 2, 1995-03.

The subject bed mover and the optional integrated bed moving technology of the predicate device and the externally attached bed moving technology of the other predicate device included in this submission are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 14 2008

Ms. Karen M. Russell
Business Development
International Retail Services Group, LLC
12230 NE Woodinville Drive, Suite A
Woodinville, Washington 98072

Re: K072598
Trade/Device Name: IRSG Bed Mover
Regulation Number: 21 CFR 880.6910
Regulation Name: Wheeled Stretcher
Regulatory Class: II
Product Code: FPO
Dated: March 26, 2008
Received: March 27, 2008

Dear Ms. Russell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

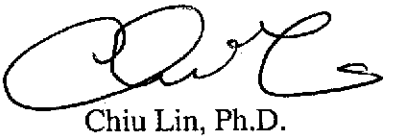
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements

of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K072598
Device Name: **IRSG Bed Mover**

Indications for Use:

The bed mover is intended to assist a single operator in the moving of wheeled beds and stretchers from one location to another within a healthcare facility.

Examples of usage include:

- a single operator may move empty beds to staging or storage areas within the healthcare facility.
- a single operator may move patient-laden beds from one location to another within the healthcare facility.

Prescription Use _____ **AND /OR** **Over-the-counter Use** X

(part 21 CFR 801 Subpart D) **(21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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